REMARKS

Claims 1-10 are pending in this application. By this Amendment, claims 1-10 are amended. Support for the amendments can be found in the specification as originally filed, for example, at page 4, lines 22-24; page 5, lines 8-10; page 6, lines 23-25 and page 10, lines 16-24; and in original claims 1-10. No new matter is added by these amendments.

The courtesies extended to Applicant's representative by Examiner Barnhart and Supervisory Examiner Marx at the interview held January 12, 2006, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute Applicant's record of the interview.

I. Claim Objection

The Office Action objects to claims 1-10 for informalities in the claims. Applicant respectfully submits that the amendments to claims 1-10 correct any informalities. Accordingly, withdrawal of the objection is respectfully requested.

II. Claim Rejections Under 35 U.S.C. §112

The Office Action rejects claims 1-10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In particular, the Office Action asserts that the phrase "the pentose-containing substrate contains a smaller amount of hexose monomers than pentose monomers" in independent claim 1 is confusing. The Office Action requires clarification as to whether this phrase means that a greater number of <u>types</u> of pentose monomers than <u>types</u> of hexose monomers are present or that more <u>molecules</u> of pentose monomers than <u>molecules</u> of hexose monomers are present.

Applicant respectfully submits that independent claim 1 is clear on its face and that claims 1-10 are not indefinite. Specifically, the phrase "the pentose-containing substrate contains a smaller amount of hexose monomers than pentose monomers" would be easily

understood by one of ordinary skill in the art to mean that there are more total pentose monomers - of any type - present in the pentose-containing substrate than total hexose monomers - of any type - present in the pentose-containing substrate. That is, one of ordinary skill would understand that any number of pentose monomer types and any number of hexose monomer types may be included in the claimed pentose-containing substrate, so long as the total number of pentose monomer molecules exceeds the total number of hexose monomer molecules.

Further, it is clear from the specification that the pentose-containing substrate of the claims may include mixtures of pentose and hexose sugars. In particular, the specification sets forth that "[w]hile several microorganisms can efficiently ferment the glucose component in cellulose, conversion of the pentose sugars contained in the hemicellulose fraction of biomass has proven more difficult." *See* Specification, page 1, lines 24-27. The specification also indicates that "[x]ylose, arabinose and other pentoses are liberated from hemicellulosic materials by treatment with steam and/or an acid or alkali. Smaller amounts of other sugars such as glucose are also separated during this treatment and are also fermented by the moderately thermophilic *Bacillus* species to lactic acid and/or lactate. ... Both pentose and hexose sugars may be simultaneously or separately fermented into lactic acid and/or lactate using the moderately thermophilic *Bacillus* species." *See* Specification, page 5, lines 8-13; page 5, lines 27-30. These passages clearly indicate that the pentose-containing substrate contains both pentose sugars and hexose sugars, such as glucose, and that the pentose sugars are present in a larger amount than the hexose sugars.

For at least these reasons, the language of independent claim 1 is clear on its face. Thus, claims 1-10 are not indefinite. Reconsideration and withdrawal of the rejection are respectfully requested.

III. Claim Rejections Under 35 U.S.C. §102

The Office Action rejects claims 1 and 5 under 35 U.S.C. §102(b) over U.S. Patent No. 4,702,922 to Wiesenberger et al., taken in light of Low, Using GC to Detect Food Adulteration, at http://www.chem.agilent.com/cag/peak/peak2-97/article1.html?PF=Y. Applicant respectfully traverses this rejection.

Independent claim 1 sets forth a "process for preparation of lactic acid and/or lactate, comprising: homolactically and anaerobically fermenting in a fermentation broth a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid and/or lactate; wherein the pentose-containing substrate contains a smaller amount of hexose monomers than pentose monomers." Claim 5 depends from and incorporates all of the limitations of claim 1.

Wiesenberger teaches processes for forming highly enantiomerically pure lactic acid by fermenting fruit products using "lactic acid producing bacteria." *See* Wiesenberger, Abstract; col. 1, lines 6-11; claim 1. Low, which is directed towards determining whether food has been adulterated, discloses that apple juice, a fruit product, contains more than twice as much of the pentose sugar fructose as of the hexose sugar glucose. *See generally* Low. Based on these teachings, the Office Action takes the position that Wiesenberger anticipates independent claim 1 and its dependent claim 5. Applicant respectfully disagrees.

Wiesenberger discloses that lactic acid producing bacteria can produce highly enantiomerically pure lactic acid from fruit products, including fruit juices. *See generally* Wiesenberger. The teachings of Wiesenberger are supplemented in the Office Action by Low, but Low does not include any teachings relating to bacteria. Rather, Low teaches only using gas chromatography to detect undisclosed commercial sweeteners added to food products such as fruit juices. *See generally* Low. Low discloses glucose, fructose and sucrose content of apple juice, but does not teach using any type of bacteria to produce lactic

acid. *See generally* Low. Thus, Low is only applicable as showing hexose and pentose content of the fruit products that may have been fermented by the Wiesenberger bacteria.

Wiesenberger does not disclose fermentation by *Bacillus* bacteria, as set forth in claim 1. Wiesenberger includes very broad disclosures of "lactic acid producing bacteria," but practically discloses only strains of *Lactobacillus* bacteria. *See* Wiesenberger, col. 2, lines 34-35; col. 3, line 1; col. 5, lines 10-35. However, the claimed *Bacillus* bacteria and the *Lactobacillus* disclosed in Wiesenberger are separate bacterial genuses that have different characteristics and properties. *See generally* Bergey's Manual of Systematic Bacteriology, Vol. 2 1104-1129, 1208-1219 (Peter H. A. Sneath et al. eds. Williams & Wilkins 1986) (attached). For example, members of genus *Bacillus* are characterized as endospore-forming, Gram-positive rods (*see* Bergey's, page 1104, Table 13.1), while genus *Lactobacillus* bacteria are characterized as regular, nonsporing, Gram-positive rods (*see* Wiesenberger, col. 5, lines 30-31; Bergey's, page 1208, Table 14.1; page 1208, col. 1). Because *Bacillus* and *Lactobacillus* bacteria are classified differently and have different characteristics, one of ordinary skill in the art would not understand a reference that discloses "lactic acid producing bacteria" and specifically recites only *Lactobacillus* bacteria, to encompass *Bacillus* bacteria. And one of ordinary skill would not replace a member of either group of bacteria with a member of the other with a reasonable expectation of having similar results and successes.

In addition, Wiesenberger does not disclose moderately thermophilic bacteria, as required by claim 1. Growth of the Wiesenberger bacteria occurs between 15 and 45°C and growth of new bacteria is negative at 45°C. *See* Wiesenberger, col. 5, lines 40-41; col. 6, line 39. That is, no bacterial growth occurs at or above 45°C. Fermentation by the Wiesenberger bacteria occurs between 15 and 40°C. *See* Wiesenberger, col. 5, lines 3-9. Practically, Wiesenberger discloses fermentation only at 33°C. *See* Wiesenberger, Table II. In contrast, the *Bacillus* of the claims are moderately thermophilic, and, for example, may be

grown anaerobically and may cause fermentation of pentose sugars at temperatures of from 30-60°C. *See* Specification, page 4, lines 22-25; page 9, lines 4-24; page 11, Table 1.

For at least the reasons set forth above, Wiesenberger, alone or in light of Low, does not teach a method that includes "homolactically and anaerobically fermenting in a fermentation broth a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid and/or lactate," as set forth in independent claim 1. Thus, claims 1 and 5 are patentable over Wiesenberger in light of Low. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Claim Rejections Under 35 U.S.C. §103

A. Green in view of Payot

The Office Action rejects claims 1-10 under 35 U.S.C. §103(a) over PCT International Publication No. WO 03/008601 A2 to Green et al. in view of Payot et al., "Lactic Acid Production by *Bacillus Coagulans* - Kinetic Studies and Optimization of Culture Medium for Batch and Continuous Fermentations," ENZYME AND MICROBIAL TECHNOLOGY, Vol. 24, 1999, pp.191-199. Applicant respectfully traverses this rejection.

Independent claim 1 is as set forth above. Claims 2-10 depend, directly or indirectly, from claim 1 and incorporate all of the limitations thereof.

The Office Action takes the position that the combination of Green and Payot would have rendered the pending claims obvious because Green teaches using *Bacillus coagulans* and *Bacillus smithii* to ferment a chemically defined medium in microaerophilic conditions to produce lactic acid and Payot teaches production of lactic acid by *Bacillus coagulans* including separation of the biomass from the culture medium and separation of lactic acid from the culture medium. Applicant respectfully disagrees.

Green discloses converting monosaccharides into lactic acid by fermentation using thermophilic bacteria, such as those of the *Bacillus* species. *See* Green, page 3, lines 8-11;

page 4, lines 24-32. In particular, Green discloses aerobic assays using *Bacillus smithii* and *Bacillus coagulans* to produce lactate from arabinose, fructose, glucose and xylose. *See* Green, page 6, lines 23-24; page 7, line 9 - page 10, line 17.

Green teaches that its disclosed bacteria may be facultative anaerobes; however, the term "facultative anaerobe" does not refer in any way to the fermentation process. A facultative anaerobic bacteria can grow under both aerobic and anaerobic conditions. *See* Michael T. Madigan et al., Brock Biology of Microorganisms 158 (Paul F. Corey et al. eds. Prentice Hall 2000) (attached). However, this term does not suggest that anaerobic fermentation is an obvious alternative to aerobic fermentation for such bacteria; practically, facultative anaerobes are used for fermentation under aerobic conditions because they grow better with oxygen. Green teaches only aerobic fermentation --fermentation in an environment that must contain oxygen-- of hexose and pentose sugars into lactic acid by *Bacillus* bacteria. While the Office Action admits that Green does not teach anaerobic fermentation or separation of the biomass or product, it relies on Payot for its teachings on these subjects.

Payot discloses fermentation of molassas by *Bacillus coagulans*. *See generally* Payot. The Office Action asserts that Payot teaches that "anaerobic fermentation of lactic acid by *Bacillus coagulans* is preferable." Applicant respectfully disagrees with this characterization of Payot. Payot teaches the effects of aeration on biomass and lactic acid production. *See* Payot, paragraph bridging pages 193-194. Specifically, Payot teaches that cultures that were aerated had an increased biomass and decreased lactic acid production. *Id.* However, Payot does not provide any specific teachings or suggestions about the effects of anaerobic conditions, but only that cultures could be affected by aeration. *Id.* That is, Payot supports the conclusion that additional aeration of aerobic *Bacillus coagulans* cultures affects biomass and lactic acid production, but does not support any conclusions relating to anaerobic

conditions. Applicant respectfully submits that one of ordinary skill in the art would not have been motivated to use anaerobic conditions to ferment a sugar-containing substrate to lactic acid by *Bacillus* bacteria, based on the teachings of Green and Payot.

In addition, the fermentation broth of Green is taught to be a combination of monosaccharide (pentose and hexose) sugars and disaccharide sugars. *See* Green, page 3, lines 18-31. Green teaches that its fermentation broth may contain specific pentose and hexose sugars, which are converted in specific percentages to lactic acid, but nowhere discloses or suggests a fermentation broth that contains more pentose than hexose monomers. *See generally* Green. Because, as admitted by the Office Action, the molasses substrate of Payot does not meet the limitations of a "pentose-containing substrate contains a smaller amount of hexose monomers than pentose monomers," Payot cannot remedy this shortcoming of Green.

The Office Action also asserts that the skilled artisan would have been motivated to substitute the fermentation broth and molasses of Green and Payot with a pentose-containing sugar source to increase the amount of lactic acid produced. However, no support is provided for this assertion. In fact, there is no suggestion in either reference that a chemically different sugar source would improve lactic acid production. *See generally* Green; Payot. At most, the combined teachings of Green and Payot might motivate a skilled person to use <u>aerobic</u> conditions and <u>hexose</u>-containing substrates, in contrast to the claimed <u>anaerobic</u> conditions and <u>pentose</u>-containing substrate. Thus, the combination of Green and Payot does not teach or suggest the claimed pentose-containing substrate.

For at least the reasons set forth above, Applicant respectfully submits that the combination of Green and Payot would not have rendered obvious independent claim 1 or its dependent claims. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. <u>Wiesenberger in view of Low, Payot and Sabinsa Corp.</u>

The Office Action rejects claims 1-10 under §103(a) over Wiesenberger, in view of Low, Payot, and Sabinsa Corp., Lactospore: Lactobacillus sporogenes: A superior probiotic, at http://www.lactospore.com/back2.htm. Applicant respectfully traverses this rejection.

Independent claim 1 is as set forth above. Claims 2-10 depend, directly or indirectly, from claim 1 and incorporate all of the limitations thereof.

As discussed above, neither Wiesenberger, in view of Low, nor Payot teaches or suggests a method that includes "homolactically and anaerobically fermenting in a fermentation broth a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid and/or lactate," as set forth in independent claim 1. Thus, Wiesenberger, Low and Payot, individually and in combination, cannot support a rejection under §103 of claims 1-10.

The Office Action relies on Sabinsa as supporting its position that substituting the claimed *Bacillus* bacteria for the *Lactobacillus* disclosed in Wiesenberger would be expected to be reasonably successful by one of skill in the art. Specifically, the Office Action asserts that Sabinsa establishes that *Bacillus coagulans* is of the same genus as *Lactobacillus* species, because *Bacillus coagulans* was originally named *Lactobacillus sporogenes*. While this assertion does summarize the first paragraph of Sabinsa, the reference goes on to state that *Lactobacillus sporogenes* exhibits characteristics typical of members of the *Lactobacillus* genus and the *Bacillus* genus and that there is no documented similarity between *Bacillus coagulans* and *Lactobacillus sporogenes*. *See* Sabinsa, page 1, first and second paragraphs. In fact, Sabinsa states that, despite being classified under genus *Bacillus* in Bergey's, *Lactobacillus sporogenes* is more closely related to *Lactobacillus*. *See* Sabinsa, paragraph bridging pages 1 and 2. Thus, Sabinsa, taken in its entirety, does not teach or suggest that

Bacillus coagulans --or any *Bacillus* bacteria-- would or could be suitably substituted for *Lactobacillus sporogenes* --or any *Lactobacillus* bacteria. *See generally* Sabinsa.

In addition, Wiesenberger does not disclose *Lactobacillus sporogenes* as suitable for its purposes. *See generally* Wiesenberger. Rather, Wiesenberger discloses only five types of *Lactobacillus*: *Lactobacillus casei*, *Lactobacillus bavaricous*, *Lactobacillus aqilis*, *Lactobacillus yamanashiensis* and *Lactobacillus ruminis*. *Id.* Each of the *Lactobacillus* disclosed by Wiesenberger can be clearly identified by classic *Lactobacillus* characteristics, unlike *Lactobacillus sporogenes*. Thus, even if Sabinsa did teach that *Bacillus coagulans* and *Lactobacillus sporogenes* belong to the same genus, one of ordinary skill would not have been motivated to substitute *Bacillus coagulans* or other *Bacillus* bacteria for the *Lactobacillus* disclosed in Wiesenberger.

Further, Sabinsa does not teach or suggest anaerobic fermentation, regardless of its teachings regarding *Lactobacillus sporogenes*. At most, Sabinsa teaches that *Lactobacillus sporogenes* and/or *Bacillus coagulans* may form lactic acid. Because *Bacillus* and *Lactobacillus* bacteria are classified differently and have different characteristics, one of ordinary skill in the art would not understand a reference that discloses "lactic acid producing bacteria" and specifically recites only *Lactobacillus* bacteria, to encompass *Bacillus* bacteria. And one of ordinary skill would not replace a member of either group of bacteria with a member of the other with a reasonable expectation of having similar results and successes.

For at least these reasons, Sabinsa cannot remedy the shortcomings of Wiesenberger, Low and Payot, and no combination of Wiesenberger, Low, Payot and Sabinsa teaches or suggests a method that includes "homolactically and anaerobically fermenting in a fermentation broth a pentose-containing substrate by a moderately thermophilic *Bacillus* species to form lactic acid and/or lactate," as set forth in independent claim 1. Thus, independent claim 1 and its dependent claims 2-10 are patentable over Wiesenberger, Low,

Payot and Sabinsa, individually and in combination. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-10 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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WPB:JMS/jms

Attachments:

Bergey's Manual of Systematic Bacteriology, Vol. 2 1104-1129, 1208-1219 (Peter H. A. Sneath et al. eds. Williams & Wilkins 1986).

Michael T. Madigan et al., Brock Biology of Microorganisms 158 (Paul F. Corey et al. eds. Prentice Hall 2000)

Petition for Extension of Time

Date: February 10, 2006

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